PPG INDUSTRIES, INC.

POLLUTION PREVENTION FRAMEWORK

FINAL PROJECT AGREEMENT

PROJECT XL

SEPTEMBER 14, 2000

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I. INTRODUCTION

A. What is Project XL?

The U.S. Environmental Protection Agency (EPA) created Project XL, which stands for *eXcellence and Leadership,* to give companies, communities, state and local agencies, federal facilities, and industrial sectors, the opportunity to propose cleaner, cheaper, and smarter ways of protecting the environment. Project XL provides real world tests of these innovative strategies. Project XL also provides a vehicle for EPA to consider and, after careful evaluation of the project, replace or modify regulatory requirements, policies or procedures if it is determined that the XL project will produce Superior Environmental Performance (SEP) and promote accountability to the public.

Project XL was identified as the best mechanism for developing an innovative Project involving EPA and PPG Industries, Inc. (PPG). Project XL provides a mechanism for the Parties to explore flexibility in EPA's Toxic Substances Control Act (TSCA) standard review process for the screening of new chemical substances, while also ensuring a superior environmental outcome.

The Pennsylvania Department of Environmental Protection (PADEP) is not a direct project participant because states do not have a delegated role in the implementation or enforcement of the Toxic Substances Control Act (TSCA), which governs manufacturing of new chemical substances. However, even though PADEP does not have jurisdiction over this program, it is committed to efforts that advance pollution prevention concepts. Also, PADEP is supportive of regulatory agency programs that provide new and innovative ways to interact with the regulated community. As a result, PADEP is committed to supporting the PPG XL Project in any way that it can.

B. Project Description and Purpose

The EPA Office of Prevention, Pesticides and Toxic Substances (OPPTS) has developed a set of computerized risk screening tools that have the potential to significantly advance pollution prevention objectives. The Pollution Prevention (P2) Framework is an approach to risk screening that incorporates pollution prevention principles in the design and development of chemical substances. The objective of the P2 Framework approach is to inform decision making at early stages of new chemical product development and to promote the selection and application of safer chemical substances and processes. These methodologies have been developed over a 20-year period by EPA and others in the scientific community to screen new chemical substances in the absence of data. Annually, EPA evaluates approximately two thousand (2000) Pre-Manufacture Notifications (PMNs) that are submitted to the Agency pursuant to Section 5 of TSCA. The Act requires that persons who manufacture (or import) a new chemical substance provide such notice to EPA 90

days prior to commencing nonexempt commercial manufacture. However, the law does not require that the submitter conduct laboratory tests to evaluate the potential hazard and risk of the new chemical substance. If the Agency does not take regulatory action within 90 days of receipt of the PMN, the submitter may manufacture that new chemical substance. Operating under this time limitation, and often lacking sufficient data, EPA has developed methods to quickly screen chemical substances in the absence of data. In an outreach effort to industry, the Agency is making the P2 Framework methodologies available and is demonstrating how these tools can help design safer chemical substances, reduce waste generation, and identify other P2 Framework opportunities. Industry response to the incorporation of EPA's P2 Framework into the chemical development process has been positive.

PPG proposes to apply the P2 Framework early in its new product development process to help it identify and develop products and processes that can be sustained both environmentally and economically. Applying the P2 Framework as a part of its new product development process, PPG will incorporate environmental and health information into the early stages of its chemical development operations as well as identify opportunities for pollution prevention. PPG is planning on using the P2 Framework at three Research and Development (R&D) facilities located at Monroeville, Allison Park, and Harmarville; all are located in the greater Pittsburgh, PA area. PPG believes many other companies can develop environmentally preferable products by applying the P2 Framework, especially at the R&D stage of product development.

The use of the P2 Framework will assist PPG when it is designing new chemical substances and products by enabling PPG to conduct an analysis similar to that performed by EPA for each PMN that is submitted to EPA. PPG will incorporate information obtained from use of the P2 Framework methodologies into its TSCA Section 5 submissions.

Unless the requirements for an exemption are met, a PMN submitter may not manufacture a new chemical substance until 90 days after it has submitted a PMN, even if information submitted to EPA indicates that the chemical substance will not present an unreasonable risk. However, when EPA determines during its initial review that a PMN chemical substance does not present an unreasonable risk to the environment or human health, the substance is not likely to be regulated by EPA. Therefore, PPG and EPA have agreed that, with respect to PMN substances that meet these criteria, based on PPG's initial pre-submission screen of the PMN materials using the P2 Framework and EPA's own review, PPG will be allowed to begin manufacture of such substances after 45 days rather than 90 days. For more detail on this issue see Section IV. B. of this Agreement, which includes a detailed description of the standards applicable to the availability of this administrative flexibility.

PPG's Project includes a series of innovative actions to help demonstrate to other chemical manufacturers how the P2 Framework can help develop products that are sustainable both environmentally and economically, while saving companies significant resources. This Project also includes several outreach initiatives for the purpose of promoting the use of the P2 Framework. Each initiative is designed to make other industry representatives aware of the source reduction, pollution prevention and economic benefits that can be realized by using the P2 Framework.

PPG, in partnership with the EPA, is entering into this Project XL Agreement to (1) pilot the application of the P2 Framework, (2) validate selected P2 Framework models and (3) disseminate information about the P2 Framework to other chemical companies and industries. Each initiative is designed to make other industry representatives aware of the source reduction, pollution prevention and economic benefits that can be realized by using the P2 Framework.

Potential environmental benefits of this Project include:

- potential health and environmental hazardous/risks as well as pollution prevention opportunities will be identified at an early stage in new product development by using the information obtained from the P2 Framework;
- the P2 Framework allows PPG to select fewer hazardous materials for use in a final product thereby reducing the production of both hazardous and solid waste materials; and
- the P2 Framework will give PPG the necessary tools to compare alternative product decisions involving chemical substances that lack environmental, health and safety data.

C. Description of Facility and Geographic Area

PPG is a leading global supplier of coatings, continuous-strand fiberglass, flat and fabricated glass, and chemicals. PPG is composed of 15 strategic business units in the four major product areas. The business units include automotive glass, automotive replacement glass, flat glass, aerospace products, architectural coatings, automotive coatings, automotive refinish, industrial coatings, packaging coatings, chlor-alkali and derivatives, fine chemicals, optical products, silica products, electronics specialty fiber glass, and reinforcement fiber glass. The Company has about 50 production facilities in the United States and 110 worldwide, including subsidiaries, joint venture, and equity affiliates. The Company employs approximately 32,500 people worldwide. The Environment, Health, and Safety (EH&S) policy of PPG is to manufacture, sell, and distribute products worldwide in a manner that is safe and protective of PPG's employees, neighbors, customers and other Stakeholders, and the environment. In fulfilling its policy, PPG has made a commitment to continuous improvement toward the ultimate goal of zero accidents, illnesses and environmental incidents. This commitment includes participation in, and support of, the chemical industry's

Responsible Care® and the coatings industry's Coatings Care Initiatives™. Each strategic business unit is responsible for planning and implementing its activities in a manner consistent with the policy and its guiding principles. The corporate EH&S Department is responsible for assisting the operating units with their obligation to carry out this policy, its goals and objectives. The EH&S Department consists of approximately 100 professionals in areas of environmental engineering, industrial hygiene, toxicology, health, and safety.

PPG has been recognized for its EH&S efforts and has received the following awards during the last 12 months: (1) Recognition on Occupational Safety and Health performance in China, (2) the Louisiana Governor's Community Outreach and Involvement Award and Governor's Environmental Leadership Award, (3) Operation for six years with no away-from work incidents in Canada, (4) the Responsible Care Pollution Prevention Award of the Ohio Chemical Council, and (5) the Director's Award for Superior Pollution Prevention of the Ohio EPA.

PPG has been a technological leader for 116 years. The Company has introduced many products and process innovations. PPG submits many new chemical notifications to EPA each year. New chemical substances have been developed in PPG's R&D facilities located at Monroeville, Allison Park, and Harmarville, all are located in the greater Pittsburgh, PA area. PPG will use the P2 Framework for its new product development process. Because PPG is incorporating the P2 Framework models in its new product development process, it will be able to develop safer products and to assess environmental and health risks of chemical substances using P2 Framework models. This is consistent with PPG's EH&S policy.

D. Purpose of this Final Project Agreement

This Final Project Agreement (Agreement) describes the intentions of EPA and PPG related to the development and implementation of this Project. The Agreement was available for a fourteen-day (14) public comment period. Like all Project XL Agreements, the Agreement itself is not legally binding, This Agreement will allow EPA to gather data and evaluate experiences that will inform Agency decision making as the Agency considers ways to improve the current regulatory system. As with all XL Projects, the opportunities granted in connection with this Agreement, in and of itself, establish no precedent with regard to other projects.

The Parties enter into this Agreement to accomplish four principal purposes. They are:

1. To describe how PPG intends to attain measurable SEP and to describe related commitments made by PPG.

2. To describe EPA commitments regarding the flexibility needed by PPG to accomplish the SEP described in this Agreement.

3. To state that the Parties do not intend to create legal rights or obligations by this Agreement

4. To describe mechanisms by which EPA intends to implement the provisions described in this Agreement.

E. List of Parties that Will Sign the Agreement

This Agreement is entered into by the Assistant Administrator of the U.S. Environmental Protection Agency Office of Prevention, Pesticides and Toxic Substances and the Vice President, Environmental Health & Safety of PPG. It will guide the working relationship of all Parties in fulfilling the promise of the PPG P2 Framework Project XL.

F. List of Project Contacts

Each party has designated a representative to serve as its contact person for inquiries concerning the Project. These representatives are as follows:

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II. DETAILED DESCRIPTION OF THE PROJECT

A. What is the P2 Framework?

The Agency encourages chemical manufacturers to incorporate health and environmental considerations into product decision making during the development of new chemical substances. EPA has several ongoing initiatives intended to help Stakeholders better assess risk issues during the early stages of product development efforts. Examples include the Design for Environment Program, the Green Chemistry Program, and the P2 Framework, among other programs. Of specific relevance to this Agreement is the P2 Framework as utilized in the development of safer new chemical substances described in PMNs submitted pursuant to Section 5 of TSCA.

The P2 Framework is an approach to risk screening that incorporates pollution prevention principles in the design and development of chemical substances. The objective of the P2 Framework approach is to inform decision making at early stages of development and promote the selection and application of safer chemical substances and processes. This approach is implemented by means of a set of computer models that predict risk-related properties of chemical substances using structure activity relationships (SARs), exposure assessment tools and models, and standard (default) scenarios. These models have been developed over a 20-year period by EPA's OPPTS to screen new chemical substances in the absence of data.

Annually, EPA evaluates more than 2,000 new chemical substances submitted pursuant to Section 5 of TSCA. TSCA requires that EPA evaluate the chemical substances within 90 days; however, the law does not require that the PMN submitter conduct laboratory tests to evaluate potential hazard and/or risk of the chemical substances. Operating under this time limitation, and often a lack of data, EPA has developed methods to quickly screen chemical substances in the absence of data.

The P2 Framework Models listed in Appendix A - P2 Framework Models, reflect the expertise of multiple EPA scientists, grantees, support contractors, as well as others in the scientific community, working for more than 20 years screening chemical substances in the absence of data. The P2 Framework Project presents these 18 models to industry with the hope that the models will be useful in identifying potential problem chemical substances and processes early in the R&D process. The table also provides information regarding the availability of the models.

The P2 Framework, as currently constructed, does not address all biological endpoints. It is a screening-level methodology that is of most value when chemical-specific data are lacking.

B. Description of Specific Project Elements

EPA expects that PPG's use of the P2 Framework to pre-screen its product development options will result in increased opportunities for pollution prevention. For example, PPG can use the P2 Framework to compare potential hazards and risks of product alternatives in R&D/product development. This effort will allow PPG to identify environmentally preferable products and processes. Further, the P2 Framework is expected to allow companies to improve the environmental performance (i.e., lower health hazard, lower environmental hazard, and lower exposure potential) of products, possibly reducing costs, decreasing potential liability, and improving market share -- resulting in a competitive advantage. EPA and PPG predict that the early use of this screening tool by companies that submit PMNs will discourage the submission of PMNs for substances that might present an unreasonable risk to human health or the environment. Anticipating and addressing EPA's concerns prior to PMN submission greatly decreases the probability of adverse regulatory action.

EPA will monitor and evaluate PPG's outreach efforts on an annual basis. PPG will report annually to EPA regarding the dates and fora/venues used by PPG to reach out to technical staff. PPG has committed to completing the following activities as part of this XL Project.

1. <u>Apply the P2 Framework</u>

   PPG will apply the P2 Framework for new product development programs and will submit with future Section 5 notifications, the results of applying the P2 Framework models. It is anticipated that PPG's use of the P2 Framework will result in the identification and development of environmentally preferable products and processes.

   PPG's XL Proposal deals with new and innovative ways of improving new product development practices. Each year EPA receives 2,000 or more new chemical notifications. Many PMNs lack the data that are necessary to fully characterize the potential risk that might be presented by new chemical substances described therein. Thus, if a company has several chemical substances from which to choose, but lacks relevant risk-related data on the available alternatives, it might choose to commercialize a particular chemical substance without the benefit of understanding all of its potential health or environmental effects.

   In this Agreement PPG is committing to using the P2 Framework in its new

product development efforts and to submit to the Agency, as appropriate, the results of P2 Framework analysis for chemical substances that will become the subject TSCA Section 5 submittals. PPG has had experience with the use and interpretation of P2 Framework methodologies, including practical experience in using the P2 Framework to differentiate among chemical substances based on risk and to identify and selectively commercialize environmentally preferable products and processes.

2. Publishing a Validation Report
   Scientific review and validation of screening-level assessment methodologies, such as those used in the P2 Framework, is central to advancement of the scientific state-of-the-art in chemical substance risk screening. In this component of PPG's Project, PPG will work with EPA to analyze the scientific validity of structure activity relationships in a major component of the P2 Framework. PPG has conducted a series of comprehensive aquatic toxicity studies on approximately 40 polymeric new chemical substances. PPG will work with EPA to use Ecological Structure Activity Relationships Software (ECOSAR) to conduct structure activity relationship analyses on these 40 polymeric new chemical substances. ECOSAR is the component of the P2 Framework used to predict potential toxicity of chemical substances to the aquatic environment (i.e., fish, invertebrates, and algae). PPG and EPA will use ECOSAR to generate aquatic toxicity predictions for each of the 40 polymeric substances and then compare the results of the ECOSAR-generated aquatic toxicity predictions with experimental data on these same chemical substances developed by PPG. This analysis will help provide a quantitative estimation of the validity of ECOSAR as a predictor of potential aquatic toxicity for this class of chemical substances.

3. Communicate with other industries on the uses and benefits of the P2 Framework
   PPG plans on communicating with, reaching out to, and working with scientific and technical staff from a variety of chemical companies and Stakeholders, to support their implementation of the P2 Framework. In conjunction with EPA, PPG will attend 2-3 seminars, meetings, or workshops per year for the duration of the Project to provide information on the benefits of the P2 Framework. These efforts will educate other chemical industry sectors on how they could benefit through reduced product development costs, reduced liability, and reduced time to market as a result of early application of the P2 Framework.

III. HOW THE PROJECT WILL MEET THE PROJECT XL ACCEPTANCE CRITERIA

The PPG Project, described in this Agreement, meets EPA's Project XL criteria. See 60 Fed. Reg. 27, 282, et seq. (May 23, 1995). The criteria and the basis for stating that they are met are summarized below.

A. Anticipated Superior Environmental Performance

The use of the P2 Framework by PPG through this Agreement will help to foster the development of new "environmentally-preferable" product development processes at PPG as well as in other chemical producing companies. As a result, it is anticipated that manufacturing processes and waste handling processes will operate at higher levels of environmental performance in the pollution prevention hierarchy (source reduction vs. reuse, recycling, treatment or disposal).

Each year approximately two thousand (2000) TSCA Section 5 notifications are received by EPA. These chemical substances often are developed to optimize product performance. In general, very little health or environmental data exist concerning such new substances. Chemical substances selected for commercialization based only on performance features might have varying degrees of environmental risk.

The P2 Framework provides a mechanism to promote data analysis beyond what is currently available by incorporating the following parameters (among others) into chemical development: structure activity relationships, a cancer expert system, property estimation techniques, and exposure assessment methodologies. The P2 Framework then generates important risk related parameters of chemical substances based on an analysis of chemical structure. The Framework is quick and easy to use, is relatively inexpensive, and can be applied before a chemical substance is synthesized. The use of an inexpensive system of assessing risk early in the product development process, where environmental data are very limited, allows health and environmental performance to be factored into the product design.

This XL Project seeks to demonstrate the source reduction and P2 benefits of moving the chemical substance evaluation process "upstream" in the product development process to a point where there are frequently multiple materials, which could eventually become final products. In moving upstream, the information supplied by using the P2 Framework can be used to differentiate among otherwise equivalent chemical substance alternatives based on risk-related considerations. Comparing alternatives based on risk allows companies to select chemical substances that are less hazardous for use in final products and can be used to identify and avoid the generation of hazardous waste. In addition, the P2 Framework can be used at other times when companies must make chemical substance decisions, but lack health and safety data on product alternatives. By sharing expertise and success stories of using the P2 Assessment Framework, PPG would promote "green chemical" selection in both its commercialization efforts and those of other companies. In using the P2

Framework as recommended by the XL Project, the P2 Framework becomes a tool for risk reduction programs, source reduction programs, and other pollution prevention initiatives.

PPG's XL Project includes three specific project elements that demonstrate SEP (see Section II. B. for a description of these elements). Each of these three elements represents a voluntary commitment to go above and beyond currently required practices and the environmental performance criteria specified by the current regulatory system. Taken together, these three elements paint a picture of a progressive company. In fact, PPG's activities under this Agreement are anticipated to provide a high level of SEP.

B. Anticipated Benefits

1. *Improving the Flow of the Innovative Process:* PPG invests hundreds of millions of dollars each year in developing new and improved products and technologies as well as adapting current technologies to new markets. New product development and product improvements are a major part of R&D at PPG. Each new product goes through several different stages from the point an idea is submitted through manufacture of the product. Significant costs are associated with each stage of new product development. When a new product candidate is dropped at any stage in the process of product development, the process must be restarted with another candidate. Previously, the P2 Framework methodologies were applied by EPA at the end of the product development during the 90-day PMN review process, just prior to the commercialization of the product. If PPG drops pursuit of the product due to potential regulation by EPA at this late stage, on the basis of potential health and environmental concerns, the impact is significant to the Company since tremendous resources have been spent on the product. By using the P2 Framework methodologies in the early stage of product development, a chemical substance candidate with human health and environmental risk concerns can be identified and addressed without the loss of significant time and resources.

2. *Bringing Products to Market More Quickly:* The P2 Framework affords a reliable, inexpensive, and rapid way of evaluating environmental risks presented by product alternatives before product development begins. By screening out potentially hazardous materials early, PPG will greatly increase the probability that product development efforts will proceed efficiently, yielding an "environmentally-preferable" product at significantly reduced cost. Anticipating EPA concerns will allow PPG to engineer environmentally preferable products and to generate needed data in a timely manner. This in turn allows PPG to get to market as soon as possible, resulting in an increased market share. If this proposal is implemented, PPG will gain the ability to

manufacture new chemical substances soon after the regulatory decision is made, and eliminate a portion of the waiting period during which EPA performs no further evaluation on low risk products.

C. Stakeholder Involvement

The Stakeholder Involvement Plan (SIP), Appendix B - Stakeholder Involvement Plan for PPG XL Project, is intended to supplement previous activities and describe the basic method by which additional input can continue to be solicited and received throughout the duration of the Project. Stakeholder input will also help to further develop the program specifics and evaluate Project performance.

Most of the new product development activities will occur at PPG R&D centers located in the Pittsburgh, PA area. PPG is reaching out to interested local and national environmental groups and local affected communities. Further, PPG's public communication committee will keep Stakeholders informed of any significant activities related to this proposal.

Public meetings will be held to inform the general public about the Project and to invite their comments and participation. The first public meeting was held on July 27, 2000, in Pittsburgh, PA, to introduce the public to the Project and the Agreement development process. Other public meetings may be held during implementation of the Agreement based on public interest or as decided by the direct participants. Public meeting locations will be chosen to provide adequate size and accessibility to all who wish to attend.

Stakeholder input has been and will continue to be considered throughout implementation of the Project. PPG will maintain and update the SIP, if needed, to provide for continued Stakeholder involvement over the duration of this XL Project.

D. Innovative Approach and Multi-Media Pollution Prevention

EPA's pollution prevention criterion expresses EPA's preference for protecting the environment by preventing the generation of pollution rather than by controlling pollution once it has been created. Pollution prevention is a central aspect of this proposal. The P2 Framework, devised by OPPT, is an innovative approach to assessing chemical substances where existing data are limited. Early application of the P2 Framework in a product development cycle is a best practice among companies that are attempting to design products with minimal environmental impact. The sharing of this technology by EPA and the communication of its benefits by PPG represents a cooperative approach to pollution prevention.

E. Transferability

The early assessment of chemical substances to prevent pollution is easily transferred to other industries. The purpose of the public outreach elements of this proposal is to

enable transfer of the P2 Framework and a pollution prevention philosophy. The premise of the P2 Framework is pollution prevention through technology transfer. The entire focus is to demonstrate that EPA's methodologies included in the P2 Framework are indeed totally transferable to the industry and that these methods can drive P2 outcomes.

F. Feasibility

PPG's business managers support this Project and are willing to provide the technical and financial support necessary to incorporate this Project into the new product development process, subject to the availability of appropriated funds. EPA has provided information, training, and technical assistance on the P2 Framework to PPG. This assistance will continue through the duration of this XL Project, subject to the availability of appropriated funds.

G. Evaluation, Monitoring and Accountability

1. Each TSCA § 5 notice submitted by PPG under this Agreement will be evaluated by EPA. Only PMN chemical substances that are determined by EPA to present no or low health or environmental risk by Day-30 of EPA's review will qualify for the regulatory flexibility discussed in Section IV.B.6. PPG will provide copies of results of P2 Framework model evaluations (e.g., computer printouts where appropriate) with notices submitted under this Agreement. EPA will use model results submitted by PPG to evaluate PPG's use and application of the P2 Framework. PPG will report annually to EPA information on notices for which the risk screen has been utilized applying the P2 assessment and provide a report summarizing the advantages of using the P2 Framework assessment process.

2. EPA will monitor and evaluate PPG's efforts relating to this component on an annual basis. PPG will report annually regarding the dates and fora/venues used by PPG to reach out to technical staff. Examples might include participating in EPA-sponsored P2 Framework workshops or training sessions. Other examples might include presenting papers or discussions regarding the P2 Framework at industry or academic seminars, participating in conferences or scientific meetings, publishing papers in scientific or technical journals or other publications, etc.

3. As part of this Agreement, PPG, working with EPA, will conduct a validation study of the use of ECOSAR in the evaluation of potential aquatic toxicity of polymeric chemical substances. PPG has agreed to complete this effort within one year of completion of the Agreement. The Agency will monitor and evaluate progress on this issue by participating in the development, review and evaluation of the validation study, participate in identifying strategies for

dissemination of the validation study, etc.

H. Shifting of Risk Burden

EPA and PPG have analyzed Executive Order No. 12898 on Environmental Justice, and do not expect the Project to result in unjust or disproportionate environmental impacts. No group of citizens or neighborhood will be subject to disproportionate environmental impacts. This proposal does not involve shifting a risk burden from one population to another or one media to another. Moreover, any person or organization expressing interest in this Project has been welcomed to participate as a Stakeholder.

IV. DESCRIPTION OF THE REQUESTED FLEXIBILITY AND THE IMPLEMENTING MECHANISMS

A. Requested Flexibility

TSCA is a law regulating aspects of the manufacture, importation, processing, distribution, use and disposal of chemical substances. Section 5 of TSCA regulates new chemical substances. Section 5 requires a manufacturer or importer to submit a PMN to EPA for a new chemical substance at least 90 days prior to commencing commercial manufacture of that substance. During the 90-day PMN review period, EPA determines whether the substance may present an unreasonable risk to human health or the environment. EPA's initial review process is completed within 20 to 25 days from the Agency's receipt of a notice. PPG will submit information obtained from the P2 Framework with its TSCA Section 5 submissions. This will aid EPA's risk assessment process. PPG and EPA have agreed that PMN substances reported by PPG that meet EPA's criteria may be manufactured prior to day 90 of the review period pursuant to a Test Marketing Exemption (TME). For a more in-depth discussion of the requested flexibility see Appendix C - Regulatory Flexibility.

B. Legal Implementation Mechanism

Concurrent Submissions: Under this Agreement, for chemical substances for which PPG uses the P2 Framework, PPG may submit combination TME applications and PMNs for concurrent review by EPA. Although EPA generally discourages such simultaneous submittals, for purposes of encouraging the use of EPA's P2 Framework, PPG will be permitted to make such submissions pursuant to this Agreement. EPA will allow such concurrent submissions to be sustained when the TME is granted and the corresponding PMN is dropped from further review during the first 30 days of the review period. Possible outcomes of EPA's review are that the TME may be approved or denied by EPA and the PMN may be regulated (e.g., under a Section 5(e) Order and/or a Section 5(a)(2) SNUR) or "dropped" from further review (i.e., EPA allows the statutory, 90-day review period to expire without regulating the chemical).

General Interpretation: The terms of this Agreement are consistent with, and require compliance with, all applicable statutory provisions and regulations under TSCA. In particular, PMNs are governed by TSCA Section 5 and 40 CFR Part 720, and TMEs are governed by TSCA Section 5(h)(1) and (6) and 40 CFR 720.38. To the maximum extent possible, this XL project will operate under the regular rules and policies of the TSCA §5 New Chemicals Program. For example, manufacture under the TME must be for genuine test marketing purposes and must be determined by EPA not to present an unreasonable risk to human health and the environment.

TME Approval and PMN Drop

Between Day-45 and Day-90: If EPA approves the TME, PPG may commence manufacture for test marketing purposes 45 days after submitting the TME to EPA. Thus, between Day-45 and Day-90, PPG may manufacture, pursuant to the TME requirements, but it may not manufacture the chemical substance for nonexempt commercial manufacture until the 90-day PMN review period expires.

After Day-90: If both the TME is granted and the corresponding PMN is dropped, then the following applies:

1. PPG may commence nonexempt commercial manufacture of the chemical substance (even if the stated TME period has not expired). According to 40 CFR 720.102(b)(1), PPG must submit a notice of commencement (NOC) of manufacture "on, or no later than, 30 calendar days after the first day of [nonexempt commercial] manufacture or import." Upon EPA's receipt of the NOC, the chemical substance will be placed on the TSCA Inventory of Chemical Substances and will no longer be a "new chemical"under TSCA.

2. PPG may sell or use for nonexempt commercial purposes quantities of the chemical substance that were manufactured under the TME, however, PPG may not submit an NOC until it first commences nonexempt commercial manufacture.

TME Denial and/or PMN Regulation

Concurrent submissions will be sustained only when the TME is granted by EPA and the corresponding PMN is dropped from further review during the first 30 days of the review period. If EPA denies the TME, PPG will be unauthorized to commence manufacture of the chemical substance between Day-45 and Day-90, but EPA will continue to review the PMN and take action as needed. If EPA grants the TME, but does not drop the PMN during the first 30 days of review, PPG will be notified that it must choose, by letter within 15 days of being notified of the Agency's decision, to continue only one of the two notification procedures (i.e., withdraw the TME and continue with the PMN, or continue the TME and withdraw the PMN). In the event that PPG elects to withdraw a TME or PMN, PPG may later resubmit such a notice for

the same chemical substance for EPA's reconsideration.

Under the terms of this XL Project, PPG remains responsible for complying with all requirements and provisions of both the TME and the relevant PMN, including the maintenance of proper records and filing of all appropriate and necessary production notices. PPG shall maintain clear records indicative of its dates and levels of production demonstrating that it is operating in compliance with the applicable terms of the pertinent TME or PMN. Nothing in this Agreement relieves PPG of its duty to comply with currently applicable regulatory requirements governing pre-manufacture authorization for the production of new chemical substances.

Additional discussion of the processes which the parties anticipate will be followed in submitting the simultaneous submissions and maintaining clarity in the manufacturing approval process are contained in Appendix D - Mechanics of Simultaneous Submissions of TMEs and PMNs.

C. Why Is this Flexibility Appropriate?

EPA and PPG believe the flexibility described above is appropriate for this Project. All Parties' intentions are to grant flexibility to this Project as a result of the combination of unique elements listed below.

1. This project will promote the use of risk screening tools to develop more environmentally-benign chemical substances, resulting in:

   - development of environmentally preferable new chemical products by allowing more effective screening for human and environmental risks early in product development, when change is most cost effective;
   - expansion of use of the Agency's P2 Framework screening models in the chemical manufacturing and formulating industries;
   - transferability of the P2 Framework screening models to other companies; and
   - increasing innovation in R&D.

2. Other benefits include the following:

   - the establishment of a structured industry program employing human health and environmental risk evaluation of product alternatives before commercialization/ manufacture (pollution prevention through technology transfer);
   - an industry advocate promoting the use of the P2 Framework;
   - when opportunities arise, PPG will share its expertise in the use of the P2 Framework with the scientific and business communities from various chemical and coatings companies; and

- PPG will complete and publish a validation study to verify the accuracy of the P2 Framework by comparing aquatic toxicity data from the P2 Framework models with data from toxicity testing.

V. DISCUSSION OF INTENTIONS AND COMMITMENTS FOR IMPLEMENTING THE PROJECT

A. PPG Intentions

- PPG will comply with all regulatory requirements during implementation of this Project.

- Apply the P2 Framework in PPG's new product development programs.

- Publish a validation report and/or present the results of the validation effort at scientific or technical meetings, in a joint effort with EPA, which will evaluate the P2 Framework models used to predict aquatic toxicity of polymeric substances based on the analysis of the structure.

- Communicate with, reach out to, and work with scientific and technical staff from a variety of chemical companies and Stakeholders, to support their implementation of the P2 Framework by participating in 2-3 meetings or workshops per year.

- PPG will work with Stakeholders and the appropriate local, regional, state and federal agencies to facilitate the process, as appropriate.

- PPG intends to continue to provide resources to maintain the schedules set forth in Section V. E.

B. EPA Intentions

- EPA will facilitate, in a timely manner and through use of Project XL, the regulatory flexibility requested by PPG.

- EPA will work with Stakeholders and the appropriate local, regional, state and federal agencies to facilitate the process.

- EPA will review the Project to determine whether it results in SEP.

- EPA intends to continue to provide resources and technical support to PPG, subject to the availability of appropriated funds, to achieve the objectives of this Agreement and to maintain the schedules set forth in Section V. E.

C. Project XL Performance Targets

EPA will evaluate the results of this Agreement to determine performance relating to the following measures:

1. Though this Agreement, and other related activities, EPA seeks to learn if pollution prevention and risk screening methodologies, such as those contained in the P2 Framework, can yield chemical-specific information that assists companies in the identification of environmentally preferable new chemical substances and helps in the identification of pollution prevention opportunities.

2. Development of a validation study detailing the predictive capabilities of the ECOSAR as it relates to predictive toxicity of polymeric chemical substances.

3. To use PPG's active participation in 2-3 scientific meetings or conferences per year as a vehicle for informing others in the chemical industry about the P2, risk screening and source reduction benefits of the P2 Framework.

D. Proposed Schedule and Milestones

Under this Agreement, PPG agrees to the following three (3) milestones and associated schedule:

1. Milestone One: PPG will apply the P2 Framework in new product development operations. PPG will provide copies of results of P2 Framework model evaluations, e.g., computer printouts, where appropriate, with PMNs submitted under this Agreement.

   Schedule for Milestone One: PPG will begin submission of P2 Framework evaluations with the first PMN submitted by PPG after the signing of this Agreement.

2. Milestone Two: Communicating with, reaching out to, and working with scientific and technical staff from a variety of companies, to support awareness and implementation of the P2 Framework and/or other risk screening methodologies.

   Schedule for Milestone Two: PPG will engage in two (2) or more outreach efforts within one year of signature of this Agreement.

3. Milestone Three: Completion of a Validation Study of the application of ECOSAR in the evaluation of aquatic toxicity of polymeric chemical substances.

Schedule for Milestone Three: PPG, with the support of EPA, will complete and disseminate the Validation Study of the aquatic toxicity of polymeric chemical substances within one year of signature of this Agreement.

E. Project Tracking, Reporting and Evaluation

For the duration of this Agreement, PPG will provide an annual summary report to EPA and, upon request, to Stakeholders. PPG will make all Project data and reports available to Stakeholders on request. The first annual report will be due one year following the signing of this Agreement. Succeeding annual reports will be due the same time each year during the life of this Agreement.

In each annual report PPG will provide a summary of environmental performance data and will describe its progress toward completing the Project as described in this Agreement. The report should describe progress on all of the voluntary commitments contained in this Agreement. Other reports produced as part of the Project which address these subjects may be used as appropriate. An annual public meeting will be held, if deemed necessary, after the first annual report is issued. Reasonable advance meeting notice will be provided to the Agencies and Stakeholders. If a public meeting is scheduled, PPG or its representative will present the report to the Stakeholders at the public meeting.

1. Report Frequency and Content
   EPA and PPG will work together to draft a report outline within ninety (90) days of the signature of this Agreement. To the extent possible and consistent with applicable regulations, the outline will be structured so that streamlining of reporting on voluntary activities could continue beyond the duration of this Agreement. The report will include, but not be limited to: Stakeholder activities; achieved milestones; important announcements; and, a schedule for activities through the next reporting period. Inclusion of all relevant information in one report will streamline reporting for the Project and make information about progress available on a reliable schedule in a consistent format.

2. Uses of Information
   Nothing in this Agreement reduces or affects PPG's rights to copyright, patent, or license the use of any proprietary or business confidential information or data contained in or created in the course of the implementation of this Project.

F. Periodic Review by the Parties to the Agreement

The Parties to this Agreement will hold periodic performance review conferences to assess their progress in implementing the PPG XL Project. Unless they agree otherwise, the date for those conferences will be concurrent with annual Stakeholder

Meetings. No later than thirty (30) days following a periodic performance review conference, PPG will provide a summary of the minutes of that conference to all Direct Stakeholders. Copies of any additional comments from participating Stakeholders will be forwarded onto EPA.

G. Duration of the Project

This Agreement will continue for three years. After year three, both PPG and EPA will conduct an independent program evaluation. If both PPG and EPA desire to continue the Agreement, the Agreement will be extended for a period of time mutually agreed upon by EPA and PPG, with input from interested Stakeholders.

VI. LEGAL BASIS FOR THE PROJECT

A. Authority to Enter into the Agreement

By signing this Agreement EPA and PPG acknowledge and agree that they have the respective authorities, discretion, and resources to enter into this Agreement and to implement all applicable provisions of this Project, as described in this Agreement.

B. Legal Effect of the Agreement

This Agreement states the intentions of the Parties with respect to the PPG XL Project. The Parties have stated their intentions seriously and in good faith, and expect to carry out their stated intentions.

This Agreement does not create or modify legal rights or obligations, is not a contract or a regulatory action, such as a permit or a rule, and is not legally binding or enforceable against any Party. Rather, it expresses the plans and intentions of the Parties without making those plans and intentions binding requirements. This applies to the provisions of this Agreement that concern procedural as well as substantive matters. While all Parties fully intend to adhere to these, they are not legally obligated to do so.

This Agreement is not a "final agency action" by EPA, because it does not create or modify legal rights or obligations and is not legally enforceable. This Agreement, itself, is not subject to judicial review or enforcement. Nothing any Party does or does not do that deviates from a provision of this Agreement, or that is alleged to deviate from a provision of this Agreement, can serve as a basis for any claim for damages, compensation or other relief against any Party.

C. Applicability of Other Laws or Regulations

The Parties do not intend that this Agreement will modify the applicability of any existing or future laws or regulations.

D. Retention of Rights to Other Legal Remedies

Nothing in this Agreement affects or limits PPG's or EPA's legal rights. These rights may include legal, equitable, civil, criminal or administrative claims or other relief regarding the enforcement of present or future applicable federal and state laws, rules, regulations or permits with respect to the facility.

Although PPG does not intend to challenge Agency actions implementing the XL Project (including any rule amendments or adoptions, permit actions, or other action) that are consistent with this Agreement, PPG reserves any right it may have to appeal or otherwise challenge any EPA or local action to implement the Project. With regard to the legal implementing mechanisms, nothing in this Agreement is intended to limit PPG's rights to administrative or judicial appeal or review of those legal mechanisms, in accordance with the applicable procedures for such review.

VII. UNAVOIDABLE DELAY DURING PROJECT IMPLEMENTATION

"Unavoidable delay" (for purposes of this Agreement) means any event beyond the control of any Party that causes delays or prevents the implementation of the Project described in this Agreement, despite the Parties' best efforts to put their intentions into effect. An unavoidable delay can be caused by, for example, a fire or acts of war.

When any event occurs that may delay or prevent the implementation of this Project, whether or not it is avoidable, the Party to this Agreement who knows about it will immediately provide notice to the remaining Parties. Within ten (10) days after that initial notice, the Party should confirm the event in writing. The confirming notice should include: (1) the reason for the delay; (2) the anticipated duration; (3) all actions taken to prevent or minimize the delay; and (4) why the delay was considered unavoidable, accompanied by appropriate documentation.

If the Parties, agree that the delay is unavoidable, relevant parts of the Project schedule (see Section V.D.) will be extended to cover the time period lost due to the delay. If they agree, they will also document their agreement in a written amendment to this Agreement. If the Parties don't agree, then they will follow the provisions for Dispute Resolution outlined below.

This Section applies only to provisions of this Agreement that are not implemented by legal implementing mechanisms. Legal mechanisms, such as permit provisions or rules, will be subject to modification or enforcement as provided under applicable law.

VIII. AMENDMENTS OR MODIFICATIONS TO THE AGREEMENT

This Project is an experiment designed to test new approaches to environmental protection and there is a degree of uncertainty regarding the environmental benefits and costs associated with activities to be undertaken in this Project. Therefore, it may be appropriate to amend this Agreement at some point during its duration.

This Agreement may be amended by mutual agreement of all Parties at any time during the duration of the Project. The Parties recognize that amendments to this Agreement may also necessitate modification of legal implementation mechanisms or may require development of new implementation mechanisms. If the Agreement is amended, EPA and PPG expect to work together with other regulatory bodies and Stakeholders to identify and pursue any necessary modifications or additions to the implementation mechanisms in accordance with applicable procedures. If the Parties agree to make a substantial amendment to this Agreement, the general public will receive notice of the amendment and be given an opportunity to participate in the process, as appropriate.

In determining whether to amend the Agreement, the Parties will evaluate whether the proposed amendment meets Project XL acceptance criteria and any other relevant considerations agreed on by the Parties. All Parties to the Agreement will meet within ninety (90) days following submission of any amendment proposal (or within a shorter or longer period if all Parties agree) to discuss evaluation of the proposed amendment. If all Parties support the proposed amendment, the Parties will (after appropriate Stakeholder involvement) amend the Agreement.

IX. TRANSFER OF PROJECT BENEFITS AND RESPONSIBILITIES TO A NEW OWNER

The Parties expect that the implementing mechanisms will allow for a transfer of PPG's benefits and responsibilities under the Project to any future owner or operator upon request of PPG and the new owner or operator, provided that the following conditions are met:

PPG will provide written notice of any such proposed transfer to the EPA at least ninety (90) days before the effective date of the transfer. The notice is expected to include identification of the proposed new owner or operator, a description of its financial and technical capability to assume the obligations associated with the Project, and a statement of the new owner or operator's intention to take over the responsibilities in the XL Project of the existing owner or operator.

Within forty-five (45) days of receipt of the written notice, the Parties expect that EPA will determine whether: (1) the new owner or operator has demonstrated adequate capability to meet EPA's requirements for carrying out the XL Project; (2) is willing to take over the responsibilities in the XL Project of the existing owner or operator; and (3) is otherwise an appropriate Project XL partner. Other relevant factors, including the new owner or operator's record of compliance with Federal, State and local environmental requirements, may be considered as well.

It will be necessary to modify the Agreement to reflect the new owner and it may also be necessary for EPA to amend appropriate rules, permits, or other implementing mechanisms

(subject to applicable public notice and comment) to transfer the legal rights and obligations of PPG under this Project to the proposed new owner or operator.

X. PROCESS FOR RESOLVING DISPUTES

Any dispute which arises under or with respect to this Agreement will be subject to informal negotiations between the Parties to the Agreement. The period of informal negotiations will not exceed twenty (20) calendar days from the time the dispute is first documented, unless that period is extended by a written agreement of the Parties to the dispute. The dispute will be considered documented when one party sends a written Notice of Dispute to the other Parties.

If the Parties cannot resolve a dispute through informal negotiations, the Parties may invoke non-binding mediation by describing the dispute with a proposal for resolution in a letter to the EPA Assistant Administrator for the Office of Prevention, Pesticides and Toxic Substances. The Assistant Administrator will serve as the non-binding mediator and may request an informal mediation meeting to attempt to resolve the dispute. The Assistant Administrator will then issue a written opinion that will be non-binding and does not constitute a final EPA action. If this effort is not successful, the Parties still have the option to terminate or withdraw from the Agreement, as set forth in Section XI below.

XI. WITHDRAWAL FROM OR TERMINATION OF THE AGREEMENT

A. Expectations

Although this Agreement is not legally binding and any party may withdraw from the Agreement at any time, it is the desire of the Parties that it should remain in effect through the expected duration of three years, and be implemented as fully as possible unless one of the conditions below occurs:

1. Failure by any party to (a) comply with the provisions of the enforceable implementing mechanisms for this Project, or (b) act in accordance with the provisions of this Agreement. The assessment of the failure will take its nature and duration into account.

2. Failure of any party to disclose material facts during development of the Agreement.

3. Failure of the Project to provide SEP consistent with the provisions of this Agreement.

4. Enactment or promulgation of any environmental, health or safety law or regulation after execution of the Agreement, which renders the Project legally, technically or economically impracticable.

5. Decision by an agency to reject the transfer of the Project to a new owner or operator of the facility.

In addition, EPA does not intend to withdraw from the Agreement if PPG does not act in accordance with this Agreement or its implementation mechanisms, unless the actions constitute a substantial failure to act consistently with intentions expressed in this Agreement and its implementing mechanisms. The decision to withdraw will, of course, take the failure's nature and duration into account.

PPG will be given notice and a reasonable opportunity to remedy any "substantial failure" before EPA's withdrawal. If there is a disagreement between the Parties over whether a "substantial failure" exists, the Parties will use the dispute resolution mechanism identified in Section X of this Agreement. EPA retains its discretion to use existing enforcement authorities, including withdrawal or termination of this Project, as appropriate. PPG retains any existing rights or abilities to defend themselves against any enforcement actions, in accordance with applicable procedures.

B. Procedures

The Parties agree that the following procedures will be used to withdraw from or terminate the Project before expiration of the Project term. They also agree that the implementing mechanism(s) will provide for withdrawal or termination consistent with these procedures.

1. Any party that wants to terminate or withdraw from the Project is expected to provide written notice to the other Parties at least sixty (60) days before the withdrawal or termination.

2. If requested by any party during the sixty (60) day period noted above, the dispute resolution proceedings described in this Agreement may be initiated to resolve any dispute relating to the intended withdrawal or termination. If, following any dispute resolution or informal discussion, a party still desires to withdraw or terminate, that party will provide written notice of final withdrawal or termination to the other Parties.

3. The procedures described in this Section apply only to the decision to withdraw or terminate participation in this Agreement. Procedures to be used in modifying or rescinding any legal implementing mechanisms will be governed by the terms of those legal mechanisms and applicable law. It may be necessary to invoke the implementing mechanism's provisions that end authorization for the Project (called "sunset provisions") in the event of withdrawal or termination.

XII. COMPLIANCE AFTER THE PROJECT IS OVER

The Parties intend that there be an orderly return to compliance upon completion, withdrawal from, or termination of the Project, as follows:

A. Orderly Return to Compliance with Otherwise Applicable Regulations, if the Project Term is Completed

If, after an evaluation, the Project is terminated because the term has ended, PPG will return to compliance with all applicable requirements by the end of the Project term, unless the Project is amended or modified in accordance with Section VIII of this Agreement (Amendments or Modifications). PPG is expected to anticipate and plan for all activities to return to compliance sufficiently in advance of the end of the Project term. PPG may request a meeting with EPA to discuss the timing and nature of any actions that PPG will be required to take. The Parties should meet within thirty days of receipt of PPG's written request for such a discussion. At and following such a meeting, the Parties should discuss in reasonable, good faith, which of the requirements deferred under this Project will apply after termination of the Project.

B. Orderly Return to Compliance with Otherwise Applicable Regulations in the Event of Early Withdrawal or Termination

In the event of a withdrawal or termination not based on the end of the Project term and where PPG has made efforts in good faith, the Parties to the Agreement will determine an interim compliance period that provides sufficient time for PPG to return to compliance with any regulations deferred under the Project. The interim compliance period will extend from the date on which EPA or PPG provides written notice of final withdrawal or termination of the Project, in accordance with Section XI of this Agreement. By the end of the interim compliance period, PPG will comply with any applicable standards. During the interim compliance period, EPA may issue an order, permit, or other legally enforceable mechanism establishing a schedule for PPG to return to compliance with otherwise applicable regulations as soon as practicable. This schedule cannot extend beyond six months from the date of withdrawal or termination. PPG intends to be in compliance with all applicable Federal, State, and local requirements as soon as is practicable, as will be set forth in the new schedule.

XII. SIGNATORIES AND EFFECTIVE DATE

We, the undersigned, pledge our support for the continued success of the PPG XL Project XL and the furtherance of an effective partnership between EPA and PPG.

William H. Sanders III
Director
Office of Pollution Prevention and Toxics
United States Environmental Protection Agency

David C. Cannon Jr.
Vice President
Environment, Health & Safety
PPG Industries, Inc.

SUPPORTING SIGNATORIES

The PPG XL Project enjoys the support of a broad range of public and private organizations and individuals. Our signatures below express our support for this Project and the contribution it will make to the environment and the community.

Roger Scriven, Director
Coatings R&D
PPG Industries, Inc.

David T. McKeough, Director
Chemicals R&D
PPG Industries, Inc.

Jay Benforado
Deputy Associate Administrator
Office of Policy, Economics and Innovation

Barbara Z. D'Angelo
Director
Office of Environmental Innovation
Region III
U.S. Environmental Protection Agency

APPENDIX A

P2 Framework Models

Model	*Endpoints Addressed*	*Inputs Needed*	*Availability*
Models to Estimate Physical-Chemical Properties			
EPI Suite*	Melting and Boiling Points, Vapor Pressure	CAS RN or Chemical Structure in SMILES notation	These methods were developed by Syracuse Research Corporation (SRC). Some methods were developed under contract to US EPA, OPPT in support of Section 5 of TSCA. EPIWIN is available from SRC, Syracuse, N.Y.
	Octanol / water partition coefficient		
	Water solubility from log Kow		
	Soil organic carbon partition coefficient		
	Henry's law constant: VP/WS		
	Bioconcentration factor		
Models to Estimate Environmental Fate			
EPI Suite*	Atmospheric oxidation potential	CAS RN or Chemical Structure in SMILES notation	These methods were developed by SRC. Some methods were developed under contract to US EPA, OPPT in support of Sec. 5 of TSCA. EPIWIN is available from SRC, Syracuse, N.Y.
	Biodegradation rate		
	Hydrolysis rate		
	Percent removal in POTW		
Models to Estimate Human Health and Environmental Hazards			
OncoLogic	Cancer hazard potential	Chemical structure	Developed by LogiChem under a cooperative agreement with USEPA, OPPT in support of Sec. 5 of TSCA. OncoLogic is available from LogiChem Inc., Boyertown, PA.
ECOSAR*	Aquatic toxicity to fish, invertebrates, algae	CAS RN or Chemical Structure in SMILES notation	Download at no cost from http://www.epa.gov/oppt/newchems/21ecosar.htm
Models to Estimate Exposure and / or Risk			
E-FAST	Surface water ingestion, fish ingestion, ground water ingestion, ambient air inhalation, indoor air inhalation, dermal exposure, aquatic environment exposure/risk	Physical / chemical properties, fate properties, release amounts, release medium, release location, aquatic concentration of concern, NPDES number	Download at no cost from http://www.epa.gov/opptintr/exposure
ReachScan	Impact of surface water discharges on drinking water facilities, i.e., chemical concentration downstream at drinking water intake point	Facility location (NPDES number), release data	Contact Tom Brennan at brennan.thomas@epa.gov for a free copy
Occupational Exposure Spreadsheets^	Vapor generation rates and worker exposure to vapors during filling, sampling, and to open liquid pools; and during degreasing operations; Water releases and worker exposures to powders during textile dyeing	Molecular weight, vapor pressure, operation hrs/day, worker exposure hrs/day; if applicable, volume of degreasing solvent or dye used, dye exhaustion rate	Contact Scott Prothero at prothero.scott@epa.gov for a free copy
^ "ChemSTEER," a comprehensive Windows®-based tool containing methods from these spreadsheets and many other methods for estimating workplace exposures and environmental releases from industrial and commercial operations, is currently under development.			

July 2000

DISCLAIMERS: Mention of trade names or commercial products, or services does not convey, and should not be interpreted as conveying official USEPA approval, endorsement, or recommendation.

The models presented in OPPT's P2 Framework have been developed over a period of more than 20 years by OPPT, EPA contractors and/or grantees or others in the scientific and technical community, to screen chemicals in the absence of data. Through the P2 Framework, OPPT is

presenting these screening models to industry and other stakeholders in the hopes that use of these models early in the research and development process will result in safer chemicals entering commerce. The P2 Framework models should be used for priority setting and to provide additional information so that choices can be made on the chemicals being evaluated.

Other chemical screening methodologies have been developed and are in use by chemical companies and other stakeholders. The Agency recognizes that other models are available and that these models can also be of value in chemical screening efforts.

CAUTION: Screening models predict data with an inherent degree of uncertainty, and should *never* be used to replace measured data from well designed studies. Measured data are always preferred over predicted data. If measured data are not available, measured data on close analogs can be used. If no analog data are available, screening level models, such as those in the P2 Framework, may be used for priority setting and to predict values that can be used to indicate which chemicals may need further testing or evaluation.

APPENDIX B

Stakeholder Involvement Plan for PPG XL Project

I. INTRODUCTION

Stakeholder involvement is considered essential for the success of an XL Project. This Stakeholder Involvement Plan (SIP) is intended to seek input from interested parties.

II. GOALS AND OBJECTIVES

The goal of this SIP is to ensure interested Stakeholders are afforded the opportunity to participate in the success of this Project and to provide the Stakeholders with the information they need to make decisions and provide input during Project development and implementation. The following are the objectives for this plan:

- Identify Stakeholders and their role in the Project
- Describe methods of communication between PPG and the Stakeholders
- Ensure all Stakeholders have an opportunity to participate in the Project
- Promote Stakeholder involvement in development of the Agreement

III. IDENTIFICATION OF STAKEHOLDERS

Stakeholders include any individuals, government organizations, environmental and other public interest groups, academic centers, and businesses with an interest in environmental matters concerning PPG and surrounding communities. Stakeholders provide information on the preferences of the community and may also identify unaddressed issues. Stakeholders fall into three general categories: direct participants, commentors, and the general public.

1. Direct participants work intensively on Project development from the ground up. Their views will have the most influence on the details of the Project.

2. Commentors have an interest in the Project, but do not desire to participate intensively in Project development. They will want to be kept informed on Project development, attend public meetings and provide comments and advice.

3. Members of the general public might not become directly involved in the Project, but will be given easy access to the Project development process and to information about the environmental results during Project implementation. They also have the opportunity to participate more actively if they so choose.

Contacting potential Stakeholders occurred prior to development of the Agreement.

Commentors have been put on a Project mailing list to ensure that they are informed of all opportunities to comment or participate during Project development and implementation. The following methods were used to contact and inform potential Stakeholders.

1. Local Newspapers: Legal notices were placed in local newspapers to invite the general public to public meetings and inform them of comment periods.

2. Regional Newspapers: Legal notices were placed in regional newspapers to invite the general public to public meetings and inform them of comment periods.

3. Invitations: To make national groups aware of the meetings, PPG sent e-mails to a list of organizations that EPA communicates with on a regular basis. EPA provided PPG a list of contacts.

IV. PUBLIC MEETINGS

Public meetings were held to inform the general public about the Project and to invite their comments and participation. PPG conducted public meetings at its Allison Park, Pa., and Monroeville, Pa., facilities. Other public meetings may be held during implementation of the Agreement based on public interest or as decided by the direct participants. Public meeting locations will be chosen to provide adequate size and accessibility to all who wish to attend.

Stakeholder input has been and will continue to be considered throughout implementation of the Project. PPG will maintain and update the SIP, if needed, to provide for continued Stakeholder involvement over the duration of this XL Project.

V. PPG INDUSTRIES POINT OF CONTACT

Jean Chun (412) 492-5482.

APPENDIX C

Regulatory Flexibility

A. Overview of New Chemical Substance Regulation

TSCA provides statutory authority to control the manufacturing, use, distribution in commerce and disposal of industrial chemical substances. Section 5 of TSCA provides specific authorities for controlling new chemical substances. New chemical substances are defined in Section 3(9) of TSCA as any chemical substance that is not included on the Inventory compiled under Section 8(b) of TSCA.

Section 5 requires notification to EPA at least 90 days before manufacture or processing of a new chemical substance (i.e., PMN) or prior to manufacturing or processing an existing chemical for a significant new use. EPA receives 1,500 to 2,000 submissions annually; more than 35,000 notifications have been received by the Agency since passage of TSCA. EPA's extensive experience in the review of PMNs has allowed the Agency to develop efficient mechanisms to identify new chemical substances which are of greatest concern. EPA's approach to PMN review is designed for, among other considerations, rapid identification of low risk chemical substances. EPA strives to identify low risk chemical substances early so these materials can be eliminated from review early in the PMN process, allowing the Agency to focus assessment resources on chemical substances of concern. Part of EPA's review of PMNs includes a series of highly focused meetings and assessment activities designed to characterize chemical substance assessment issues in the earliest stages of the 90-day PMN review period. These activities allow the Agency to identify low risk chemical substances that can be dropped from further Agency review, early in the review process. Low risk drops are usually identified in the first 30 days of the 90-day review process. Most PMN notices are dropped early in the review process because the Agency has concluded these chemical substances pose low risk to humans or the environment.

The PMN review period can be extended under TSCA Section 5(c) for good cause; it may also be suspended voluntarily by the mutual consent of EPA and the PMN submitter. As noted above, during the review period, EPA may take action under TSCA Section 5(e) or (f) to prohibit or limit the production, processing, distribution in commerce, use, and disposal of new chemical substances that raise health or environmental concerns. If EPA has not taken action under TSCA Section 5(e) or (f), the PMN or exemption notice submitter may manufacture or import the new chemical substance when the review period expires.

No later than 30 days after the PMN submitter initiates manufacturing or importing the PMN substance, it must provide EPA with a notice of commencement of manufacture or import (NOC). Section 8(b) of TSCA provides that, upon receipt of such a notice, EPA

must add the substance to the TSCA Inventory. Thereafter, other manufacturers and importers may engage in activities involving the new substance without submitting a PMN, unless the Agency has used its Significant New Use Rule (SNUR) authority under TSCA Section 5(a)(2) to designate a use of a chemical substance as a "significant new use." Section 5(a)(1)(B) of TSCA would then require persons to submit a Significant New Use Notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the substance for the use designated as significant. The required SNUN provides EPA with the opportunity to evaluate the intended use, and if necessary, to prohibit or limit that activity before it occurs.

B. Exemptions

The following exemptions under TSCA and its implementing regulations under Section 5(h) reduce or eliminate reporting requirements and waiting periods prior to manufacture for the products that meet their criteria:

1) Low Volume Exemption (LVE) -- 10,000 kilograms or less of the substance will be manufactured or imported each year under the requirements at (40 CFR §723.50). Notification required, using EPA Form 7710-25 (the PMN Form). Manufacture may begin 30 days after notification for qualifying products.

2) Research and Development -- the substance is manufactured in small quantities for R&D, and special procedural and record keeping requirements are met (40 CFR §§720.36 and .78). Notification is not required.

3) Low Releases and Low Exposures (LoREX) -- the substance is expected to have low release and exposure under the requirements at 40 CFR §723.50. Notification required, using the PMN Form. Manufacture may begin 30 days after notification for qualifying products.

4) TME -- the substance is being manufactured or imported for TME, under the requirements at 40 CFR §720.38. Notification required, using the PMN Form. Manufacture may begin 45 days after notification for qualifying products.

5) Polymer Exemption -- the substance is a polymer that meets certain specified criteria where the substance is not considered chemically active or bioavailable under the requirements at 40 CFR §723.250. An annual report to the Agency is required for those exempt polymers commenced for the first time in the preceding calendar year.

C. The New Chemical Review Process

The PMN program has evolved into an efficient mechanism to identify new chemical substances which are of greatest concern during the early stages of the 90-day review process and focus detailed analysis on these cases with the ultimate goal of identifying

and controlling unreasonable risks. EPA utilizes an integrated approach that draws on knowledge and experience across EPA's scientific and organizational lines to identify and evaluate concerns regarding health and environmental effects, exposure and release and economic impacts. PMNs and exemption notices share the early stages of the 90-day PMN review process; LVE and LoREX applications conclude review by day 30 and TME applications by day 45.

The following series of meetings and activities briefly describes the elements of EPA's chemical substance assessment and screening activities in the first 30 days of the 90-day PMN review period, including: (a) The Chemical Review and Search Strategy Meeting, (b) The Structure Activity Team Meeting, (c) development of The PMN Exposure and Release Profile, and (d) the Focus Meeting.

1) The *Chemical Review and Search Strategy (CRSS)* meeting (Day 8-12) examines chemical substance identity; structure/chemical nomenclature; structural analogs/TSCA Inventory Status; synthesis (including byproducts and impurities); use/TSCA jurisdiction as provided by the PMN submitter, open literature, or as identified by EPA for similar chemical substances; physical/chemical properties (physical state, molecular weight, melting and boiling point, vapor pressure, solubility, octanol water partition co-efficient, pH); and pollution prevention aspects, using information provided by the PMN submitter. EPA also may make suggestions for alternate synthetic pathways. Decisions at this meeting include notice completeness, validity, reportability, eligibility for exemption or exclusion, candidacy for exposure-based review, and whether the notice meets certain CRSS drop criteria.

2) The *Structure Activity Team* meeting (Day 9-13) is an interdisciplinary meeting of scientists, including chemists, biologists, toxicologists, and information specialists which evaluates potential environmental fate, health effects and environmental hazards/risk through the use of Structure Activity Relationships (SAR), test data on the new chemical substance, data on structural analogs, and expert judgment.

3) The *Exposure and Release Profile* is developed by Day 10-19 and examines occupational exposure, environmental releases, environmental and consumer exposure.

4) The *Focus Meeting* (Day 15-20) is the earliest risk management meeting in the Section 5 notice review period; representatives from all Agency PMN technical disciplines are involved in this assessment. Initial decisions for chemical substance categories, exposure-based reviews, and all exemptions are developed at this meeting. For Exemptions notices, the initial decisions are to grant or deny the notice, with or without certain conditions of use specified in the notice, to which the submitter is legally bound. Focus meeting decisions for PMNs can

range from identifying the need to consider a ban or TSCA 5(e) regulation of the new chemical substance to a "drop" from further Agency review. A PMN can also continue on to a more detailed review which occupies most of the remainder of the 90-day period. Regardless of whether the Agency drops a PMN submission during the early stages of review at the Focus meeting or near the end of the statutorily mandated 90-day PMN review period, the PMN submitter is nonetheless not allowed to commence manufacture before day 90 of the review period.

D. Background of EPA's Policy

Historically, it has been EPA's policy to not allow simultaneous submission of LVE or TME Section 5 exemption notices and PMNs for the same substance. The R&D and Polymer exemptions, involving no advance notification, require no further discussion in this context. Although simultaneous submission of a LoREX exemption and PMN on the same chemical substance is theoretically allowable, the narrow exposure and release requirements of the LoREX exemption make it unlikely that allowing simultaneous submission of both notices would provide any meaningful regulatory relief to the submitter.

For LVEs, it is EPA's policy not to permit the LVE holder to submit a PMN until nine months after the date on which an LVE is approved by EPA (i.e., 90 days before termination of the one year low volume period). Further, the Agency will deny a LVE when a pending PMN submitter estimates its production volume to be greater than 10,000 kilograms per year. This policy, in interpreting the intent of the rule, places emphasis on the rule's use of the words 10,000 kilograms "per year," rather than per any lesser time period. Accordingly, EPA has denied an LVE because a PMN simultaneously submitted by the same company on the same chemical substance estimated the production volume to be more than 10,000 kilograms per year.

TME applications have been allowed in combination with PMNs only if the submitter's description clearly distinguishes the test marketing activity from full-scale commercial production or R&D. EPA's New Chemical Information Bulletin Exemptions for Research and Development and Test Marketing (1986) describes how the Agency, in order to discourage the use of simultaneous submissions to simply obtain PMN review of a chemical substance in 45 days, closely examines such submissions to determine if genuine test marketing activity is involved; if it is not, the application has been denied. Thus, it is EPA policy that following the submission of a TME application, the same company may not submit a PMN for the same chemical substance until 90 days before the end of the test marketing period specified by the company in its TME application pursuant to 40 CFR 720.38(b)(5).

E. How could EPA decide to approve a PPG TME but identify concerns with a PPG PMN on the same chemical?

In making a limited exception to its policy of discouraging simultaneous TMEs and PMNs, EPA is encouraging the use of its P2 Framework. However, EPA is requiring that PPG's TME submission must clearly distinguish the test marketing activity from full-scale commercial production or R&D. When EPA approves a PPG TME, it will have determined that test marketing the new chemical substance, under terms and conditions set out in the TME application (and any additional controls stipulated in an accompanying Federal Register notice announcing Agency approval of the TME), will not present an unreasonable risk of injury to human health or the environment. Such specific conditions of approval include a specified test market time period, production volume, number of customers, and use. Upon review of the same chemical substance when submitted as a PMN, the Agency could determine that a less restrictive production volume or distribution and use of the chemical substance than the limitations imposed under the TME may present an unreasonable risk to human health or the environment, and therefore EPA could decide to take regulatory action under TSCA Section 5(e). The Agency also reserves the right to rescind approval or modify the conditions and restrictions of a TME should any new information that comes to its attention cast significant doubt on its finding that the test marketing activities will not present any unreasonable risk of injury to human health or the environment.

F. EPA Policy on Isolated Intermediates

In some cases, chemical companies manufacture isolated intermediates that require the submission of a PMN and NOC before the chemical substance is added to the TSCA Inventory and enters commerce. An isolated intermediate might be sold in open commerce, or consumed or otherwise used by the same company producing the chemical substance. Under this Agreement, the Agency will evaluate such an isolated intermediate and, provided it meets the other XL criteria described in this Agreement, EPA will offer administrative relief for PMN/TMEs that describe open market and/or internal to the company distribution of that chemical substance.

APPENDIX D

Mechanics of Simultaneous Submissions of TMEs and PMNs

This Appendix discusses the mechanics of the simultaneous submission of TME applications and PMNs for purposes of this XL Project. PPG should include with its PMN submission, a cover letter which will clarify that it is submitting a PMN along with a request for a TME and that it is doing so as part of Project XL. Since there is no standard form for TME's, PPG may use any format provided it conforms with 40 CFR § 720.38 including the estimated volume of substance PPG intends to manufacture, the time period for test marketing, the number of people estimated to be exposed, and generally, why the proposed activities fit within the requirements and definition of test marketing. PPG will need to demonstrate effective use of the P2 Framework, or other appropriate risk screening methodologies, in its evaluation of the chemical that is the subject of the submission and/or chemical alternatives considered by the Company. Such demonstrations may be made by including in the submission copies of computer model runs or a written report summarizing the results of the information found using the computer models.

When PPG applies for an initial TME application, the Company should provide information on its proposed test market time period and production volume as well as other information required in 40 CFR § 720.38.

Suggested language for a cover letter with the joint TME/PMN submission

Enclosed are two separate TSCA Section 5 submissions for the same new chemical substance, one a TME and one a PMN. These notices are being submitted in accordance with a Final Project Agreement signed by PPG and EPA pursuant to the Agency's XL Program.